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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,738	05/18/2005	Eric Simard	24913/04004	9696

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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
10/05/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/508,738	SIMARD ET AL.	
	Examiner	Art Unit	
	MEERA NATARAJAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-12 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-12, 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments in the reply filed on 06/08/2009 are acknowledged and entered into the record.

2. Accordingly, Claims 3-12 and 14-17 are pending and will be examined on the merits.

Claim Rejections Maintained - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. The rejection of claims 3-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiserodt et al. (US Patent #6277368) in view of Ferrante et al. (Cancer Chemother. Pharmacol., Vol. 43(Suppl), p. S61-S68, 1999) is maintained for the reasons of record.

6. The claims are drawn to an anti-cancer composition comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells.

7. Hiserodt et al. teaches cellular compositions and methods of using them in cancer immunotherapy, particularly humans. "The [compositions] comprise a source of tumor-associated antigen, and a cytokine-secreting cell line (claim 11, 12, 14, 15). The compositions may be tailored for each type of cancer (claim 7 and 8) or for each subject by mixing tumor antigen with a favorable number of cytokine-producing cells, or with a cocktail of such cells producing a plurality of cytokines at a favorable ratio." (See Abstract of Patent #6277368). The whole-cell tumor compositions taught in Hiserodt et al. have been inactivated by methods known in the art, such as with toxins or irradiation (Column 12, 3rd paragraph) (claim 3-6). Example 7 of Hiserodt et al. discloses a combination method for treatment using IL4-secreting 4CI 107 cells mixed with autologous tumor cells along with adjuvant chemotherapy agents such as Cisplatin, cisplatin/cyclophaphamide, doxorubicin, or taxol (claims 9-10). Hiserodt et al. also disclose the cells or mixture of cells are in a pharmaceutical excipient (ie. carrier) used to treat patients. Hiserodt et al. does not teach all these components (tumor cells, chemotherapeutic agent, carrier) in the **same** composition. This deficiency is made up for by Ferrante et al.

8. Ferrante et al. teach the use of chemotherapeutic compounds such as taxane, paclitaxel, doxorubicin, and cisplatin, as anti-cancer agents.

9. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the components taught by Hiserodt et al. and Ferrante et al. in the same composition for therapeutic purposes such as to treat cancer. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Hiserodt et al. and Ferrante et al. because they both teach compositions useful for the same purpose, to treat cancer. The claimed product can be viewed as a composition comprising a combination of ingredients known in the art to be useful for the same purpose, i.e. In re Kerkhoven analysis (In re Kerkhoven, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (MPEP 2144.06). Hiserodt et al. and Ferrante et al. teach compositions for the use of cancer therapy.

Response to Arguments

10. Applicants argue Hiserodt et al. does not teach a single composition that contains tumor cells, chemotherapeutic agent, and carrier, as recited in claim 3 of the instant application. Moreover, Hiserodt et al. cautions that radiation therapy and adjuvant chemotherapy be used 'in a way or at a time that does not interfere with the immunogenicity of the Hiserodt compositions'. Applicants further state, Ferrante et al. does not provide the teachings and suggestions absent from Hiserodt et al. In

particular, applicants argue Ferrante et al. is not directed at enhancing the immunogenicity of compositions that contain inactivated tumor cells but is instead directed to compositions containing two chemotherapeutic agents. These arguments have been carefully considered but not found persuasive.

11. Applicants point out in the response filed 06/08/2009 that Hiserodt et al. recite that the Hiserodt compositions may be given following, preceding, in lieu of, or in combination with, other cancer therapies, however it is advised they be used in a way or time that does not interfere with the immunogenicity of the compositions. The disclosure in Hiserodt et al. that the compositions may be given in combination with other cancer therapies and the teachings provided in Ferrante et al. that taxane, paclitaxel, doxorubicin, and cisplatin, are all common cancer therapeutic agents, renders the claimed composition obvious over the cited prior art. As stated in the previous office action (mailed 12/09/2008) and re-stated above, the court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (In re Kerkhoven, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). Although Hiserodt et al. cautions one of ordinary skill in the art that radiation therapy and adjuvant chemotherapy be used in a way or a time that does not interfere with the immunogenicity of the composition, does not teach away from combining two cancer therapeutic compositions (not radiation therapy) to be administered in the same composition. Therefore the rejection of record is maintained.

12. The rejection of claims 3-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (Cancer Immunol. Immunother. 1986) in view of Ferrante et al. (Cancer Chemother. Pharmacol., Vol. 43(Suppl), p. S61-S68, 1999) are maintained for the reasons of record.

13. The claims are drawn to an anti-cancer composition comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells.

14. Wang et al. teaches a combination treatment of an anticancer agent, CL 259,763 compound, and an inactivated L1210 leukemia composition given to mice challenged with P388 murine leukemia (claim 3). The mice were vaccinated by IP injection of L1210 leukemia cells that had been irradiated with 4,400 R (Materials and Methods, p. 10) (claim 5 and 6). Wang et al. also discloses "the present study shows that CL 259,763 has a number of properties characteristic of a biological response modifier" (p.13, Discussion) and therefore teach the limitations of claims 11 and 12. Wang et al. in addition evaluated the effect of CL 259,763 on IL-2 production in tumor-bearing animals and showed that CL259,763 reversed the impairment of IL-2 production in the tumor-bearing mice. These studies meet the limitations of claim 14 and 15, by showing the presence of IL-2. Wang et al. does not teach all these components (tumor cells, chemotherapeutic agent, carrier) in the **same** composition. This deficiency is made up for by Ferrante et al.

15. Ferrante et al. teach the use of chemotherapeutic compounds such as taxane, paclitaxel, doxorubicin, and cisplatin, as anti-cancer agents.

16. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the components taught by Wang et al. and Ferrante et al. in the same composition for therapeutic purposes such as to treat cancer. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Wang et al. and Ferrante et al. because they both teach compositions useful for the same purpose, to treat cancer. The claimed product can be viewed as a composition comprising a combination of ingredients known in the art to be useful for the same purpose, i.e. In re Kerkhoven analysis (In re Kerkhoven, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (MPEP 2144.06). Wang et al. and Ferrante et al. teach compositions for the use of cancer therapy.

Response to Arguments

17. The arguments presented above are essentially the same arguments provided for the 103(a) rejection as being obvious over Wang et al. in view of Ferrante et al. Applicants argue Wang et al. does not provide motivation for one of ordinary skill in the art to add a chemotherapeutic compound to a composition comprising tumor cells. These arguments have been carefully considered but not found persuasive. As stated in the previous office action (mailed 12/09/2008) and re-stated above, the court held

that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (In re Kerkhoven, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). Therefore one of ordinary skill in the art would have been motivated to combine the cancer therapeutic composition disclosed in Wang et al. with the chemotherapeutic agents disclosed in Ferrante et al. for monotherapy anti-cancer treatment. Therefore the rejection of record is maintained.

Conclusion

18. Claims 3-12 and 14-17 are rejected.

19. No Claim is allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643